Psychometric properties of the Dutch SAQOL-39NL in a generic stroke population.

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Samenvatting

Inleiding Instrumenten om health related quality of life (HRQL) te meten zijn vaak ongeschikt voor afasiepatiënten. Recentelijk is er een Nederlandse versie ontwikkeld van de Stroke and Aphasia Quality Of Life-scale (SAQOL-39NL) bestaande uit drie domeinen (fysiek, psychosociaal en communicatie), 39 vragen en een 5-punts-antwoord schaal (0 - 5). De psychometrische eigenschappen zijn slechts gedeeltelijk onderzocht.

Doel Het evalueren van de psychometrische eigenschappen van de SAQOL-39NL in een CVA populatie.

Populatie CVA patienten met (n=59) of zonder (n=81) afasie die behandeld zijn bij Rijndam Revalidatiecentrum, Rijnlands Revalidatiecentrum of Sophia Revalidatiecentrum en zijn geincludeerd in de TEA-studie of SCORE-studie.

Methode De SAQOL-39NL en EQ5D werden op drie en zes maanden post onset afgenomen. Bodem en plafond effecten en missende data werden geanalyseerd. De interne consistentie werd geanalyseerd door de Cronbach's alpha te berekenen. Intercorrelaties tussen domeinen en totaalscores werden berekend voor de construct validiteit.

Resultaten De gemiddelde leeftijd van de patiënten was 60,4 jaar (SD 11,1), 62% was man. De gemiddelde totale SAQOL-39NL score was 3,93 (SD 0,68). Er werden geen missende data, bodem of plafond effecten gevonden. De interne consistentie was uitstekend (Cronbach's alpha = 0,96). Correlaties tussen de domeinen en de totale schaal waren goed tot uitstekend (r = 0,54-0,88). De associatie met de EQ5D was matig (r = 0,54).

Conclusie De SAQOL-39NL is een aanvaardbaar, valide en betrouwbaar instrument om de kwaliteit van leven bij patiënten met een beroerte te evalueren.

Aanbevelingen De SAQOL-39NL is klaar voor gebruik in de klinische praktijk. Verder onderzoek is nodig om te bepalen welk niveau van taalbegrip een patient met afasie moet hebben om de SAQOL-39NL te voltooien. Het is ook aan te raden om het fenomeen responsiviteit verder te onderzoeken.

Kernwoorden: afasie, kwaliteit van het leven, uitkomstmaat, SAQOL-39NL, beroerte

Abstract

Introduction Instruments to evaluate health related quality of life (HRQL) are often unsuitable for stroke patients with aphasia. Recently, a Dutch version of the Stroke and Aphasia Quality Of Life-scale (SAQOL-39NL) was developed (3 domains: physical, psychosocial and communication; 39 items; answering categories 0-5). Its psychometric properties have only been partially assessed.

Objective To evaluate the psychometric properties of the SAQOL-39NL in a generic stroke population.

Patients Stroke patients with (n=59) or without (n=81) aphasia treated in Rijndam Rehabilitation, the Rijnlands Rehabilitation Center, or Sophia Rehabilitation, who were included in either the TEA-study or the SCORE-study.

Methods The SAQOL-39NL and EQ-5D were administered 3 months after the start of rehabilitation. Acceptability was explored by assessing floor and ceiling effects as well as percentage of missing items. For internal consistency, Cronbach's alpha was calculated. For construct validity, the intercorrelations between domains and total scores, and the association with the EQ5D were assessed using Pearson's r.

Results The mean age of the patients was 60.4 years (SD 11.1), 62% were male. Mean total SAQOL-39NL score was 3.93 (SD 0.68). No missing data, floor or ceiling effects were found. Internal consistency was excellent (Cronbach's alpha = 0.96). Intercorrelations between domains and total scale were good to excellent (r=0.54 to 0.88). The association with the EQ5D was moderate (r=0.54).

Conclusions The SAQOL-39NL is an acceptable, valid, and reliable instrument to evaluate the HRQL in stroke patients.

Recommendations The SAQOL-39NL is ready for use in clinical practice. Further research is necessary to determine which level of language comprehension an aphasic patient should have to complete the SAQOL-39NL. It is also recommended to elaborate the concept responsiveness to change.

Key words: aphasia, health related quality of life, outcome measure, SAQOL-39NL, stroke

1. Introduction

Every year about 40.000 people in the Netherlands suffer a cerebrovascular accident (CVA). Approximately 25% of this population acquires aphasia. The number of strokes is likely to increase in the next couple of decades by aging (1). Furthermore, as stroke mortality rates decline (2) there is an increase in the number of individuals surviving stroke with residual impairments and disability.

Aphasia is a language disorder caused by brain damage that arises after language is acquired (3). As communication is a vital skill to participate in society, difficulties in communication, like people with aphasia have, can have a major impact on the quality of life (4).

In 2001 the World Health Organisation (WHO) introduced the International Classification of Functioning (ICF) (5). The ICF is a framework that has drawn international attention on the concept of functional health. Not only the dysfunction is treated but there is also attention for the activities, participation, internal and external factors (5). Thereby the interest of health related quality of life (HRQL) increased and became an important outcome measure in rehabilitation care (6).

For people with aphasia the focus on HRQL is particularly important, as 62-70% of this population develops a clinical depression (7). Furthermore, Hilari (8) showed that people with aphasia have a lower quality of life than stroke survivors without aphasia. It has been shown that aphasia has a negative impact on the social life and can lead to social isolation (8-11).

Measuring quality of life is a complicated process. Recently more and more instruments have been developed to evaluate the HRQL for specific disorders. Most of these instruments are not suitable for people with aphasia because the items are linguistically too complex (12). Hilari et al. (13-14) developed the Stroke and Aphasia Quality of Life scale (SAQOL-39) and the SAQOL-39g, aimed to measure HRQL in stroke patients with or without aphasia. The SAQOL-39 showed to be acceptable, reliable and valid. Several translations of the SAQOL-39 were made (14-20).

Van Ewijk et al (11) introduced a Dutch translation: the SAQOL-39NL. The first phase of validation and standardization is completed. Van Ewijk et al. (12) included 47 chronic aphasia patients to examine the acceptability, reliability and validity of the SAQOL-39NL. In this study the SAQOL-39NL was found to be acceptable, the internal consistency and test-retest reliability were excellent, and the internal validity and convergent validity were good.

The authors note that further research is needed, to assess whether this instrument is suitable for different phases in recovery after stroke and whether the list is also suitable for stroke sufferers without aphasia. A stroke-specific measure of health-related quality of life that is appropriate for use in both people with and without aphasia would allow the inclusion of people with aphasia in stroke outcome studies and comparisons of quality of life between stroke people with or without aphasia.

Moreover, the measure's responsiveness to change has not been analyzed yet. In order to use the instrument to evaluate effectiveness of therapy in clinical practice, further investigation is needed.

2. Aim

The primary objective of the present study is to evaluate the psychometric properties of the SAQOL- 39NL in a stroke population, which includes people with and without aphasia. Furthermore, responsiveness to change will be investigated by analysing data at two time points post stroke.

The availability of the SAQOL-39NL (for the generic stroke population) will not only improve the rehabilitation care for people with aphasia in the Netherlands by providing a valid and reliable outcome measure for HRQL, but will also contribute to the possibility of comparisons of outcomes across different countries.

3. Method

3.1 Design

A retrospective repeated-measures multi-centre study was carried out. Data at two time points post stroke (three months and six months) were analysed. Existing data were derived from two cohort studies (21-22). These studies are briefly described below.

The study was conducted according to the principles of the Declaration of Helsinki (27) and in accordance to the Medical Research Involving Human Subjects Act (WMO). Personal data were handled comply by the Dutch Personal Data Protection Act (Wet Bescherming Persoonsgegevens). All participants in both cohort studies have signed an informed consent. Both cohort studies were reviewed by the local research METC. The use of the data for the current study was also approved.

SCORE-study

The SAQOL-39NL is part of the Stroke Outcome Cohort Stroke REhabilitation study (SCORE) (21). A study of outcomes of post-stroke for patients with and without aphasia, which is conducted at Rijnlands Rehabilitation Centre (Leiden) and Sophia Rehabilitation (The Hague). This study focuses on functions, activities, participation, and quality of life of stroke survivors on the short and long term.

TEA-study

The SAQOL-39NL is also used in the tDCS and Aphasia study (TEA), a randomized multicenter effect study of Transcranial Direct Current Stimulation (tDCS) in stroke patients with aphasia in the sub-acute phase (22). This study aims to identify the effect of tDCS on language, the quality of life and costs of aphasia patients treated up to 6 months after stroke.

3.2 Participants

In both of the above-described projects, the SAQOL-39NL was one of the instruments used to measure outcomes. For the current study, data was included based on the following inclusion and exclusion criteria: The population of this study consists of stroke patients with and without aphasia who participate in the SCORE-study or TEA-study. People were included if they met the following criteria: aetiology: stroke, either ischaemic or haemorrhagic, including subarachnoid haemorrhage; time since stroke not longer than 6 months; age ≥18 years; written informed consent; completed the SAQOL-39NL in its entirety at two different measuring moments; for the non-aphasic population: completed the EuroQol-5D (EQ5D). A potential subject who meets any of the following criteria was excluded from participation in this study: severe psychiatric condition or premorbid dementia; inability to communicate in the Dutch language; concurrent acquired brain injury (traumatic or non-traumatic) or pre-existent brain

disease (dementia or other) that was diagnosed before the onset of stroke; drug or alcohol abuse; severe non-linguistic cognitive disturbances.

3.3 Measures

The participants completed the SAQOL-39NL at two different points in time, three and six months post onset. Participants were allowed to choose whether to filled out the questionnaire digitally or on paper. When necessary the participants were allowed to complete the questionnaires over more than one session (e.g. due to fatigue), or with help of their significant others.

Convergent validity was analysed by using the outcome on another questionnaire: the EuroQol-5D (EQ-5D). The EQ-5D is a generic instrument that provides a single index value for health status (R31). The questionnaire was found valid and reliable in several languages (32). This instrument measures the same construct as the SAQOL-39NL: HRQL. The EQ-5D was only filled out by the participants without aphasia, as the list is not suitable for aphasic patients. In most cases the Token Test (34) or ScreeLing (35) was used to determine aphasia.

SAQOL-39NL

The SAQOL-39NL contains 39 questions divided into three areas: physical, psychosocial and communication. Items were scored on a 5-point scale with one of two response formats [1= 'kon het helemaal niet' (could not do this at all), 5 = 'helemaal geen moeite' (no difficulties) and 1= 'zeker ja' (Definitely yes), 5= 'zeker nee' (Definitely no)]. The domain scores and overall score were calculated by averaging the items (11).

3.4 Psychometric evaluation and data analysis

Study parameters were: SAQOL-39NL scores, domain scores, and EQ-5D scores. Data was analysed using IBM SPSS Statistics 20 (23).

In line with Hilari and colleagues, standard psychometric methods (24-26) were used to evaluate acceptability, internal consistency, construct and convergent validity, and responsiveness to change, using the COSMIN checklist for evaluating the methodological quality of studies on measurement properties (28-29). Content validity, cross culture validity and test-retest reliability have not been examined in this study since it has already been investigated by Van Ewijk et al. (11)

The following criteria (13-14) were used:

Acceptability: missing data <10%; skewness> ±1 for no more than 25% of the items. With regards to the distributions of scores for individual items, floor and ceiling effects <80%.

Internal consistency: Cronbach's alpha (α) between 0.70 and 0.95; Item-total correlations \geq 0.30.

Internal validity: The intercorrelation between overall score and domains should be >0.30 (REF) to ensure items fit within the construct that is being measured (HRQL).

Convergent validity: Correlation between mean score SAQOL-39NL and mean score EQ-5D ≥0.30.

Responsiveness to change: Effect sizes (ES) were used to assess the responsiveness to change. ES were expressed in terms of Cohen's d and standardized response means (SRM). The next interpretation of ES (36) was used: 0.20= small ES, 0.50=moderate ES, and 0.80= large ES. In line with Hilari et al (14), we expected only small changes in SAQOL-39NL scores between three and six months.

4. Results

4.1 Participants

Data of 141 participants was analysed, 62% were male. The age of participants was perfectly normal distributed with an age range of 21 to 86 (mean=60.41 sd=11.41). Almost 76% of the participants came from the score-study and 41.8% had aphasia. Table 1 shows the participants characteristics.

4.2 Psychometric properties

In table 2 the psychometric properties are defined.

There were no missing data, floor or ceiling effects found. Twenty-one (53%) items failed the skewness criterion (skewness> ± 1 for no more than 25% of the items). The internal consistency of the SAQOL-39NL showed to be excellent with a Cronbrach's alpha of 0.96 for the overall score and 0.95 for each of the domains. Item total correlations ranged from 0.33 to 0.72 and within the domains from 0.52 to 0.88. Intercorrelations between overall scores and domains were moderate to excellent (0.54 to 0.88) and intercorrelations between domains were low to moderate (0.19 to 0.47). A moderate correlation was found between the EQ-5D and SAQO:-39NL (r=0.54).

Table 3 shows the average SAQOL-39NL scores, average domain scores, change score's, Cohen's d, and the Standardized Response Mean (SRM) responsiveness to change between the three and six months time points. Cohen's d and SRMs are both an example of effect sizes, which are widely used to assess the responsiveness to change (36). Based on Henrica et al (36), Cohen's d was calculated by the mean change score divided by the standard deviation [sd] of the baseline score. The SRM was calculated by dividing the change score by the sd of the change score. As expected there were small changes in SAQOL-39NL scores between three and six months (d = 0.04 - 0.15, SRM= 0.07 - 0.17).

5. Discussion

5.1 Key findings

The psychometric properties of the Dutch translation of the SAQOL-39 have been assessed. In line with the findings of Van Ewijk et al (11) the SAQOL-39NL demonstrated to be acceptable, valid and reliable. Different to Van Ewijk et al (11) is that this current study included stroke patients with and without aphasia, not only aphasic patients. Another difference is the sample size of the study, which is bigger in the current study and makes the findings more powerful (Van Ewijk et al. n=47, current study n=141). When combining the conclusions of both studies, the SAQOL-39NL showed to be acceptable, valid and reliable in a generic stroke population in the acute, sub-acute and chronic phase. The findings are consistent with results of Hilari et al (14) on the original English SAQOL-39.

In the introduction of this study was argued that the availability of an instrument for HRQL in stroke patients, with good psychometric properties will improve rehabilitation care and facilitate cross-linguistic and international comparison between patients. Considering the list is found to be acceptable, valid and reliable, the clinical practice is recommended to start using the SAQOL-39NL and make it usual care.

5.2 Strengths and limitations

A limitation of the study was that only three and six months data was available. It made no difference to evaluate acceptability, validity or reliability but for responsiveness to change only small changes in SAQOL-39NL scores were found. This was expected because Hilari (14) found the same results between three and six months. However, Hilari (14) did find moderate change scores between two weeks and six months. This is in line with the low to moderate improvements in quality of life after stroke (38) and the normal process of rehabilitation after stroke (39). Because all of the psychometric properties including the responsiveness to change between three and six months correspond to the findings of Hilari (14), it is likely that also the responsiveness to change of the SAQOL-39NL is sufficient.

One of the strengths of this study are the participant characteristics which is an accurate reflection of the stroke population in the Netherlands (37), except that the number of aphasic patients is higher in the current study (41.8%). This is devoting to the fact that participants in the TEA-study were all aphasia patients. Another strength is the sample size of this study (n=141) which makes the key findings powerful.

5.3 Implications for future research

A recommendation for future research is to investigate which level of language comprehension a patient should have to complete the SAQOL-39NL. There was no attention for this aspect in the current study and neither/little in international studies. Another recommendation is to

investigate and elaborate on the concept *responsiveness to change*. In international studies and in the current study there was only exploratory attention for this phenomena. However it is still unknown how meaningful a certain change score on the SAQOL-39NL actually is. The question: *what does it mean when somebody had a SAQOL-39NL score of 2 in the first place and 4 after a few months?* is still unanswered.

Nevertheless, speech and language therapists could use the SAQOL-39NL in clinical practice already because the list is sufficiently able to detect change scores. Especially between two weeks and six months. However future research is necessary to investigate how to interpret the change scores.

6. Conclusion

The SAQOL-39NL shows good internal consistency, validity, reliability, and an adequate responsiveness to change. The SAQOL-39NL is an acceptable, valid, and reliable instrument to evaluate the HRQL in stroke patients with and without aphasia. It is recommended to implement the SAQOL-39NL in Dutch clinical practice.

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Tables

Tabel 1. Participant characteristics (n=14				
Variable	Participants n (%)			
O- m do m				
Gender				
Female	53 (37,6)			
Male	88 (62,4)			
Age				
Mean [SD]	60.41 [11.14]			
Range	21-86			
18-45	10 (7,1)			
46-64	78 (55,3)			
65-74	44 (31,2)			
75+	9 (6,4)			
Stroke type				
Ischaemic	108 (76,6)			
Haemorrhagic	32 (22,7)			
Unknown	1 (0,7)			
Communication				
Aphasic	59 (41,8)			
Non-aphasic	81 (57,4)			
Unknown	1 (0,7)			
Level of education				
Lower	69 (48,9)			
Higher	63 (44,7)			
Unknown	9 (6,4)			
Cohort study				
Score-study	107 (75,9)			
TEA-study	34 (24,1)			

Tabel 2. Psychometric properties of the SAQOL-39NL at three months

Property	Results at three months		
	n=141		
Acceptability			
Sample score range (scale range)	3.2 - 4.5 (1-5)		
Mean [SD]	3.93		
Missing data (>10%)	0		
Floor effects	0		
Ceiling effects	0		
Skewness (>±1)	21 items (53%)		
Internal consistency			
Conbrach's alpha			
Overall	0.96		
Domains	Physical =0.95		
	Communication=0.95		
	Psychosocial=0.95		
Item-total correlations			
Overall	0.33-0.72		
Domains	Physical = 0.62-0.87		
	Communication= 0.70-0.88		
	Psychosocial=0.52-0.80		
Construct validity			
Internal validity			
Intercorrelations between overall	Physical = 0.80		
scores and domains (r)	Communication= 0.54		
	Psychosocial= 0.88		
Intercorrelations between domains (r)	Physical and communication = 0.19		
	Communication and psychosocial= 0.44		
	Psychosocial and physical= 0.47		
External validity			
Convergent validity			
Association with EQ-5D (n=105)	Overall: 0.54		
	Physical: 0.64		
	Communication: 0.11		
	Psychosocial: 0.40		

Table 3. Average SAQOL-39NL scores, change scores and responsiveness to change

SAQOL-39NL	Mean [SD]			Responsiveness	
		Change		3 months – 6 months	
	3 months	6 months	3 months – 6 months	d	SRM
Psysical	4.17 [0.82]	4.13 [0.83]	0.04 [0.45]	0.05	0.09
Psychosocial	3.59 [0.91]	3.71 [0.90]	- 0.12 [0.69]	- 0.13	- 0.17
Communication	4.22 [0.80]	4.34 [0.77]	- 0.12 [0.70]	- 0.15	- 0.17
Overall	3.93 [0.68]	3.96 [0.69]	- 0.03 [0.44]	- 0.04	- 0.07